Premarket Approval (PMA) Package for Dockets Management Branch

PMA Number P030035 Docket # 2004M-0250

St. Jude Medical

St. Jude Frontier™ Biventricular Cardiac Pacing System including the Frontier™ Model 5508 and 5508L Pulse Generators, the Aescula™ LV Model 1055K Lead and the Model 3307 v4.4.2m programmer software for use with the Model 3500/3510 Programmer

Includes:

Approval Order
Summary of Safety and Effectiveness Data (SSED)
Labeling

AAV/

2004M-0250